

REMARKS

Applicants note that any cancellations and/or amendments of claims made herein are made in order to further their business interests and the prosecution of the present application, yet without acquiescing to the Examiner's arguments, and while preserving the right to prosecute the canceled (or similar) claims in the future.

In the Office Action mailed 5/15/07, the Examiner objected to Claims 1 and 4-7 as containing reference to a non-elected invention. The Applicants have amended Claim 1 to remove the recitation of the non-elected invention. As such, the Applicants respectfully request that the objection be withdrawn.

In the Office Action mailed 5/15/07, the Examiner issued several rejections. Each of the rejections is discussed in detail below.

I. The Claims are Enabled

The Examiner rejects Claims 1, 2, and 4-7 as allegedly lacking enablement (Office Action, pg. 3). In particular, the Examiner states "the specification, while being enabling for a method for detecting lung cancer in a subject, comprising detecting the presence of GSTM4 polypeptide in lung tissue of said subject, does not reasonably provide enablement for a method for identifying a stage lung cancer in a subject, a method for providing a prognosis of lung cancer..." (Office Action, pg. 4). The Applicants respectfully disagree and submit that the claims are enabled as written. Nonetheless, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claim 1 to recite a method of diagnosing lung cancer based on increased expression of GSTM4 polypeptide and canceled Claims 4-7. As the Examiner has stated that such embodiments are enabled, the Applicants respectfully request that the rejection be withdrawn.

II. The Claims are Novel

In the Office Action mailed 5/15/07, the Examiner issued a series of rejections under 35 U.S.C. 102. Each of the rejections is discussed in detail below.

A. The Claims are not Anticipated by Cantlay

The Examiner rejects Claims 1, 2, and 4 as allegedly being anticipated by Cantlay et al. (Thorax, 1994, 49:1010; hereinafter Cantlay) (Office Action, pg. 10). The Applicants respectfully disagree. Cantlay does not teach the claim step of diagnosing cancer by detecting increased levels of GSTM4 relative to the levels in non-cancerous tissues. Indeed, Cantlay does not teach detection of GSTM4, but rather detects expression of GSTM1. Furthermore, Cantlay specifically states that no attempt was made to quantitate the levels of GSTM1 protein (pg. 1012, 2nd paragraph). As such, the Applicants submit that Cantlay does not teach all of the elements of the claims as required for rejection under 35 U.S.C. 102 and accordingly respectfully request that the rejection be withdrawn.

B. The Claims are Not Anticipated by Rowe

The Examiner rejects Claims 1 and 4 as allegedly being anticipated by Rowe et al. (Biochem J. 1997 325:481; hereinafter Rowe) (Office Action, pg. 10). The Applicants respectfully disagree. Rowe does not teach the claim step of diagnosing cancer by detecting increased levels of GSTM4 relative to the levels in non-cancerous tissues. As such, the Applicants submit that Rowe does not teach all of the elements of the claims as required for rejection under 35 U.S.C. 102 and accordingly respectfully request that the rejection be withdrawn.

C. The Claims are Not Anticipated by Chen (a)

The Examiner rejects Claims 1 and 4-6 under 35 U.S.C. 102 (a) as allegedly being anticipated by Chen et al. (Mol. Cell. Proteomics, 2002, 1:304; hereinafter Chen(a)) (Office Action, pg. 10). The Applicants respectfully disagree. Chen (a) does not teach the claim step of diagnosing cancer by detecting increased levels of GSTM4 relative to the levels in non-cancerous tissues. As such, the Applicants submit that Chen (a) does not teach all of the elements of the claims as required for rejection under 35 U.S.C. 102 and accordingly respectfully request that the rejection be withdrawn.

D. The Claims are Not Anticipated by Chen (b)

The Examiner rejects Claims 1, 2, and 4-7 under 35 U.S.C. 102 (a) as allegedly being anticipated by Chen et al. (Clin Cancer Res., 2002 8:2298; hereinafter Chen (b)) (Office Action, pg. 11). The Applicants disagree. The Chen (b) reference is a publication of the Applicants' own work published within the year before the filing date of the present application, and therefore, is not prior art. See, e.g., MPEP §2132.01 ("Applicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under 35 U.S.C. §102(a)." *In re Katz*, 687 F.2d 450 (CCPA 1982)). The present application claims priority to U.S. Provisional Patent No. 60/394,858, filed July 10, 2002. There were nine inventors for the present application: David G. Beer, Sharon Kardia, Thomas J. Giordano, Jeremy Taylor, Samir M. Hanash, Chiang-Ching Huang, David E. Misek, Dafydd Thomas and Rork Kuick. The Chen (b) reference issued for publication in July 2002. The Chen (b) reference lists thirteen authors: Guoan Chen, Tarek G. Gharib, Chiang-Ching Huang, Dafydd G. Thomas, Kerby A. Shedden, Jeremy M.G. Taylor, Sharon L.R. Kardia, David E. Misek, Thomas J. Giordana, Mark D. Iannettoni, Mark B. Orringer, Samir M. Hanash, and David G. Beer. A 37 C.F.R. §1.132 Declaration from Dr. David G. Beer is now provided indicating that 1) David G. Beer, Sharon Kardia, Thomas J. Giordano, Jeremy Taylor, Samir M. Hanash, Chiang-Ching Huang, David E. Misek, and Dafydd Thomas are the only listed authors who contributed to the inventive process relating to the present invention; and that 2) Guoan Chen, Tarek G. Gharib, Kerby A. Shedden, Mark D. Iannettoni, and Mark B. Orringer were not involved with the inventive process relating to the present invention, worked under Dr. Beer's supervision and direction, and were listed as co-authors of the publication in order to acknowledge their collaboration in a research program under Dr. Beer's direction. As such, per the MPEP §2132.01, the Chen (b) reference is not prior art, and the Applicants request these rejections be withdrawn.

CONCLUSION

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (618) 218-6900.

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